

Certificate

Quality Management System

EN ISO 13485:2016

EN ISO 13485:2016/AC:2018

EN ISO 13485:2016/A11:2021

Registration No.: SX 2048822-1

Certificate Holder: Tosoh Corporation
2-2-1, Yaesu,
Chuo-ku, Tokyo
104-0028 Japan

Scope: Design and Development, Manufacture, Distribution,
Installation and Service of Immunoassay analyzers,
Glycohemoglobin analyzers, Molecular testing analyzers,
Catecholamine analyzers, High performance liquid
chromatography analyzers and Microtitre plate readers.

Design and Development, Manufacture and Distribution of
Reagents, Calibrators, Controls, Buffers, Columns,
Peripherals, Consumables, Parts and Accessories

The Certification Body of TÜV Rheinland LGA Products GmbH certifies that the organization has established and applies a quality management system for medical devices.

Proof has been furnished that the requirements specified in the abovementioned standard are fulfilled. The quality management system is subject to yearly surveillance.

Report No.: 150310274-301

Effective date: 2025-08-31

Expiry date: 2028-08-30

Issue date: 2025-08-18

Replaces certificate SX 2048822-1 issued 2024-08-29

This certificate can be validated on <https://www.certipedia.com>


Atsushi Kato

TÜV Rheinland LGA Products GmbH
Tillystraße 2 · 90431 Nürnberg · Germany

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104-0028 Japan

The scope of certification also covers the following sites:

No.	Facility	Scope
/01	c/o Tosoh Corporation Bioscience Division Planning & Business Development / Sales / Marketing 2-2-1, Yaesu, Chuo-ku, Tokyo 104-0028 Japan	Aspects related to Design and Development and Distribution
/02	c/o Tosoh Corporation Research & Development / Customer Support Center 2743-1, Hayakawa, Ayase, Kanagawa 252-1123 Japan	Aspects related to Design and Development Aspects related to Intermediate Manufacture of Reagents and Controls. Aspects related to Service
/03	c/o Tosoh Corporation Planning & Business Development / Research & Development 4560, Kaisei-cho, Shunan, Yamaguchi 746-8501 Japan	Aspects related to Design and Development and Administration of Reagents, Calibrators, Controls, Buffers, Columns, Consumables and Accessories
/04	c/o Tosoh Corporation Osaka Branch Bioscience Group 4-4-9, Kouraihashi, Chuo-ku, Osaka, Osaka 541-0043 Japan	Aspects related to Distribution
/05	c/o Tosoh Corporation Nagoya Branch Bioscience Group 1-2-7, Sakae, Naka-ku, Nagoya, Aichi 460-0008 Japan	Aspects related to Distribution

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- | | | |
|-----|---|---|
| /06 | c/o Tosoh Corporation
Sendai Branch
1-11-1, Hon-cho, Aoba-ku,
Sendai, Miyagi
980-0014 Japan | Aspects related to Distribution |
| /07 | c/o Tosoh Corporation
Fukuoka Branch
3-8-10, Hakataekimae,
Hakata-ku, Fukuoka, Fukuoka
812-0011 Japan | Aspects related to Distribution |
| /08 | c/o Tosoh Techno-System Inc.
Tokyo Service Station
2-1-3, Kyobashi,
Chuo-ku, Tokyo
104-0031 Japan | Aspects related to Installation and Service |
| /09 | c/o Tosoh Techno-System Inc.
Hokkaido Service Station
1-777-12, Shinko-nishi,
Ishikari, Hokkaido
061-3241 Japan | Aspects related to Installation and Service |
| /10 | c/o Tosoh Techno-System Inc.
Hokuriku Service Station
2, Iwasekoshi-machi,
Toyama, Toyama
931-8510 Japan | Aspects related to Installation and Service |
| /11 | c/o Tosoh Techno-System Inc.
Tohoku Service Station
1-11-1, Hon-cho,
Aoba-ku, Sendai, Miyagi
980-0014 Japan | Aspects related to Installation and Service |

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104-0028 Japan

The scope of certification also covers the following sites:

- /12 c/o Tosoh Techno-System Inc. Aspects related to Installation and Service
Kanagawa Service Station /
Technical Center
2743-1 Hayakawa,
Ayase, Kanagawa
252-1123 Japan
- /13 c/o Tosoh Techno-System Inc. Aspects related to Installation and Service
Nagoya Service Station
1-2-7, Sakae,
Naka-ku, Nagoya, Aichi
460-0008 Japan
- /14 c/o Tosoh Techno-System Inc. Aspects related to Installation and Service
Osaka Service Station
4-4-9, Kouraihashi,
Chuo-ku, Osaka, Osaka
541-0043 Japan
- /15 c/o Tosoh Techno-System Inc. Aspects related to Installation and Service
Hiroshima Service Station
4-6-16, Ootemachi,
Nakaku, Hiroshima, Hiroshima
730-0051 Japan
- /16 c/o Tosoh Techno-System Inc. Aspects related to Installation and Service
Kyushu Service Station
3-8-10, Hakataekimae,
Hakata-ku, Fukuoka, Fukuoka
812-0011 Japan

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- | | | |
|-----|--|---|
| /17 | c/o Tosoh Hi-Tec, Inc.
1-37, Fukugawaminami-machi,
Shunan, Yamaguchi
746-0042 Japan | Aspects related to Design and Development, Manufacture and Service of Immunoassay analyzers, Glycohemoglobin analyzers, Molecular testing analyzers, Catecholamine analyzers, High performance liquid chromatography analyzers, Microtitre plate readers, Peripherals, Consumables, Parts and Accessories |
| /18 | c/o Tosoh Hi-Tec, Inc. (TRC)
1-37, Fukugawaminami-machi,
Shunan, Yamaguchi
746-0042 Japan | Aspects related to Design and Development and Manufacture of Reagents and Controls |
| /19 | c/o Tosoh Hi-Tec, Inc. (Tonda)
4560, Kaisei-cho,
Shunan, Yamaguchi
746-8501 Japan | Aspects related to Design and Development and Manufacture of Reagents, Calibrators, Controls, Buffers, Columns, Consumables and Accessories |
| /20 | c/o Tosoh AIA, Inc.
2, Iwasekoshi-machi,
Toyama, Toyama
931-8510 Japan | Aspects related to Design and Development and Manufacture of Reagents, Calibrators, Controls and Buffers |

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